K120412

MAY 30 2012

510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety & Effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92. The device is a Class II device called the 3M™ SpotOn™ temperature monitoring system.

Submitter
Arizant Healthcare Inc., a 3M company
10393 West 70th Street, Eden Prairie, MN 55344

Date Prepared
February 9, 2012

Trade/Proprietary Name
3M™ SpotOn™ temperature monitoring system

Common/Usual Name
Electronic thermometer

Classification Name
Thermometer, electronic, clinical

Predicate Devices
Terumo America, Inc. Thermo-Finer CoreTemp (K760948)

Intended Use
Measure, monitor, and trend body temperature of adult and pediatric patients.

Contact
David Westlin
Chief Compliance Officer and Senior Director of Regulatory Affairs

Description of Device

The 3M™ SpotOn™ temperature monitoring system consists of a disposable sensor, a control unit, a power supply cord, and an optional interface cable that allows temperature data to be transmitted to a standard YSI-400 input on a vital signs monitor.

Comparison of the Technological Characteristics of the New Device and Predicate Devices

The SpotOn temperature monitoring system is substantially equivalent to the Thermo-Finer CoreTemp (K760948).

Comparison of Technological Features

Features	SpotOn temperature monitoring system	Thermo-Finer CoreTemp
Signal processing and display	Microprocessor, LCD display	Analog circuitry, LED display, Alarm indicator
Technology	Direct-connection, zero-heat-flux thermometry	Direct-connection, zero-heat-flux thermometry
Display methods	1 channel Numerical LCD Time-series graph	2 channels Numerical LED display Time-series graph
Display ranges	25.0°C to 43.0°C	0°C to 50.0°C
Memory storage	2 hour maximum stored on sensor	None; 14 day maximum on TFR-101 chart recorder
Other capabilities	YSI-400 thermistor emulation	0-10mV analog output

Discussion of Nonclinical Studies and Clinical Tests

Non-Clinical Tests: Multiple tests were performed with the SpotOn system to confirm safety, effectiveness and compliance with applicable standards. Testing included laboratory accuracy, instrument accuracy, time response, EMC, long term stability, biocompatibility and adhesive testing. Applied or referenced standards included ISO 80601-2-56, EN 12470-4, ASTM E1112-00, IEC 60601-1, IEC 60601-1-2 and ISO 10993.

Clinical Tests: The agreement of temperature data from the Zero-Heat-Flux-Deep-Tissue-Thermometry (DTT) system and a commercial clinical thermometer was evaluated using a method comparison trial design. Either oral or rectal sites were used as the reference location, and temperature at those sites was measured with a standard clinical thermometer. The trial design was referenced to ISO 80601-2-56 and ASTM E1965-98, as recommended by the Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices in the Center for Devices and Radiological Health of the US Food and Drug Administration.
The agreement of the DTT system to predictive oral or rectal thermometry is roughly equivalent to the agreement between direct or indirect tympanic thermometry and brain parenchyma or pulmonary artery blood temperature. The mean bias observed in any subgroup was no worse than the bias between axillary and bladder temperatures.

Conclusion

The 3M™ SpotOn™ temperature monitoring system has similar technological characteristics, components, materials, and the same intended use as devices currently on the market. Further, clinical data show a substantial equivalence in the performance of these devices. Therefore, because of the similarities to the predicate device, this new device does not present any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. David Westlin
Director of Regulatory Affairs
Arizant Healthcare Incorporated
10393 West 70th Street
Eden Prairie, Minnesota 55344

MAY 30 2012

Re: K120412
Trade/Device Name: 3M™ SpotOn™ temperature monitoring system
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: April 5, 2012
Received: April 12, 2012

Dear Mr. Westlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

3M™ SpotOn™ temperature monitoring system

Indications For Use:

Measure, monitor, and trend body temperature of adult and pediatric patients.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5/29/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120412